DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 19, 2017

Laboratorios Grifols, S.A.
Marta Daniela Serra De Fortuny
Technical Director
C/can Guasch, 2
08150 Parets Del Valles, Barcelona
SPAIN

Re: K162216
Trade/Device Name: Gri-fill Peristaltic Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: September 8, 2017
Received: September 13, 2017

Dear Marta Daniela Serra De Fortuny:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang
-S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162216

Device Name
GRI-FILL PERISTALTIC SET

Indications for Use *(Describe)*

Gri-Fill Peristaltic Set fluid transfer set is an ancillary device used in conjunction with the Gri-Fill Pharmacy Compounder and ancillary Gri-Fill sets in hospital pharmacy to provide a fluid pathway through which one solution source is delivered into a final IV container. The device is not intended to be directly connected to the patient.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510k Summary (K162216)

I. SUBMITTER

Submitter name:	Laboratorios Grifols, S.A.
Submitter address:	C/ Can Guasch, 2 08150 PARETS DEL VALLES BARCELONA SPAIN
Contact person:	Marta Daniela Serra de Fortuny
Phone:	+34 93 571 03 04
Fax:	+34 93 573 09 12
e-mail:	marta.serra@grifols.com

Date Prepared: October 2nd, 2017

II. DEVICE

Device Trade Name:	GRI-FILL PERISTALTIC SET
Common Name**:**	I.V. FLUID TRANSFER SET
Regulation Name:	INTRAVASCULAR ADMINISTRATION SET
Regulatory Class:	Class II
Product Code:	LHI
Regulation Number:	880.5440

III. PREDICATE DEVICE

Predicate Device

KIRO Set, K152441

IV. DEVICE DESCRIPTION

Gri-fill Peristaltic Set is a disposable fluid transfer set for connection to a source container and to Gri-fill sets for use with the Gri-Fill Pharmacy Compounder.

It consists of a silicone tube linking a male luer-lock connector and a spike (with a 1.2 µm hydrophobic air filter) for connecting to the source container, and a female luer-lock connection, for connecting to the Gri-fill set. The silicone tube allows the set to be used with a peristaltic pump.

The Gri-fill Peristaltic Set is intended to be used by trained health-care personnel.

The product is presented sterile (SAL = 1 x 10^{-6}) in peel-pack pouches each containing 1 unit. Sterility is achieved using a validated ethylene oxide sterilization process.

Gri-fill Peristaltic Set is not intended to be used for direct patient contact.

V. INDICATIONS FOR USE

Gri-fill Peristaltic Set fluid transfer set is an ancillary device used in conjunction with the Gri-fill Pharmacy Compounder and ancillary Gri-fill sets in hospital pharmacy to provide a fluid pathway through which one solution source is delivered into a final IV container.
This device is not intended to be directly connected to the patient.

Gri-fill Peristaltic Set and its predicate device are intended to be used for fluid transfer in conjunction with their respective Pharmacy compounding systems by trained health-care personnel in the hospital pharmacy environment. Both devices are not intended to be connected directly to patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both Gri-fill Peristaltic Set and the predicate device are tubing sets with similar inlets for connection to source containers. Both the subject and predicate devices are based upon the same technological elements:

- Both devices are single use, presented sterile (SAL = 1 x 10^{-6}) and non-pyrogenic.
- Tubing – Both are silicone tubing based upon medical grade tubing.
- Input line connectors – Both have vented spike connected by luer-lock to the silicone tubing. In both devices, the female luer-lock end of the vented spike is connected to a barbed male luer-lock attached to the tubing.
- Materials – The materials used for the vented spike, the spike filter and the spike cap in both devices are identical.

- Fluid transfer mechanism – Both use a peristaltic pump for fluid transfer.

The following technological differences exist between Gri-fill Peristaltic Set and predicate device:

- Output line connectors – Gri-fill Peristaltic Set uses a luer–lock female barb connector while KIRO Set uses a luer– lock male barb connector.
- Gri-fill Peristaltic Set has a single channel silicone tubing whilst KIRO Set has a double channel silicone tubing.
- Dose range/ Accuracy – The dose range and accuracy of fluid transfer claimed for Gri-fill Peristaltic Set are different to those claimed for the KIRO Set.
- Materials – The material used for the luer-lock male barb connector in both devices is different. The luer-lock male barb connector of the Gri-fill Peristaltic Set is made of Polypropylene while in KIRO Set is made of Polycarbonate.
- Components – Gri-fill Peristaltic Set does not include any Y-connector, because is a single-channel tubing, whereas KIRO Set includes two Y-connector to connect the double-channel segments of tubing.
- Packaging – Gri-fill Peristaltic Set is packaged individually in a heat-sealed pouch made up of medical paper web sealed to a multilayer film laminate (PET/PP) whilst KIRO Set is packaged individually in a heat-sealed Tyvek/ PET pouch.
- Sterilization – Gri-fill Peristaltic Set is sterilized using ethylene oxide gas whereas KIRO Set is sterilized by gamma radiation.

In the establishment of substantial equivalence, Gri-fill Peristaltic Set is compared to the predicate device KIRO Set (K152441) as detailed in the comparison provided in the table below.

Characteristics	**Gri-fill Peristaltic Set**	**Kiro Set – K152441 Predicate Device**	**Comparison**
Indications for Use	Gri-Fill Peristaltic Set fluid transfer set is an ancillary device used in conjunction with the Gri-Fill Pharmacy Compounder and ancillary Gri-Fill sets in hospital pharmacy to provide a fluid pathway through which one solution source is delivered into a final IV container. This device is not intended to be directly connected to the patient.	The KIRO Set is a sterile, single-use, disposable ancillary device used with the peristaltic pumps in the KIRO Oncology pharmacy compounding device for the transfer of fluids into sterile powder drug vials for reconstitution of intravenous drugs or into sterile medication containers for intravenous drug administration	The Indications for Use statement for the Gri-fill Peristaltic Set is not identical to that of the predicate device. However, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.
Intended Use	Gri-Fill Peristaltic Set is a disposable component	This product would be used for fluid	Subject and predicate have

Characteristics	Gri-fill Peristaltic Set	Kiro Set – K152441 Predicate Device	Comparison
	of the Gri-Fill Pharmacy Compounder used to provide a fluid pathway through which one source substance is channeled repeatedly to an IV container. The device is NOT intended to be connected directly to the patient.	transfer in the preparation final medication containers and the reconstitution of drug vials in hospital pharmacies when used with the KIRO Oncology pharmacy compounding device.	similar intended use for fluid transfer in conjunction with their respective pharmacy compounding systems to provide a fluid pathway through which a source substance is delivered into a final IV container.
Product Code	LHI	LHI	Identical to predicate device
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Identical to predicate device
Classification	Class II	Class II	Identical to predicate device
SUBSTANTIAL EQUIVALENCE BASED UPON INTENDED USE			
Use	Single Use	Single Use	Identical to predicate device
Prescription /OTC use	Prescription Use	Prescription Use	Identical to predicate device
Pharmacy Compounding Device Specified	Gri-Fill Pharmacy Compounder	KIRO Oncology pharmacy compounding device	Subject and predicate work with their respective pharmacy compounding systems
Intended for Direct Connection to Patient	NO	NO	Identical to predicate device
Use environment	Hospital pharmacy	Hospital pharmacy	Identical to predicate device
Target users	Trained health-care personnel	Trained health-care personnel	Identical to predicate device
Sterility	Sterile; Non-pyrogenic fluid pathway	Sterile; Non-pyrogenic fluid pathway	Identical to predicate device
Sterilization	Ethylene Oxide	Gamma Radiation	Different to predicate device
Sterility Assurance Level	10^{-6}	10^{-6}	Identical to predicate device
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Identical to predicate device. Same biological tests performed.
SUBSTANTIAL EQUIVALENCE BASED UPON TECHNOLOGICAL CHARACTERISTICS			
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Identical to predicate device. Same biological tests performed.
Tubing to channel fluids	Medical Grade Silicone	Medical Grade Silicone	Identical to predicate device
Dosification Mechanism	Peristaltic Pump	Peristaltic Pump	Identical to predicate device

Characteristics		Gri-fill Peristaltic Set	Kiro Set – K152441 Predicate Device	Comparison
Closed system (fluid not in contact with any reusable part of the compounding device)		YES	YES	Identical to predicate device
Dose Range		2 ml to 3000 ml	0.5 ml to 200 ml	Different dose range as programmed through the respective pharmacy compounding devices
Accuracy		Doses from 2.0 ml to 10 ml: ±0.2 ml Doses from 10 ml to 25 ml: ±0.5 ml Doses from 25 ml to 3000 ml: ±2 %	Doses into vials: 5.0 ml to 100 ml: ±5% 1.0 ml to 4.99 ml: ±10% 0.5 ml to 0.99 ml: ±0.1 ml Doses into reservoirs: 50 ml to 200 ml: ±10% 10 ml to 49.99 ml: ±2 ml	Different accuracy claims as achieved with the respective pharmacy compounding devices.
Number of source containers		One	One	Identical to predicate device
Input line connectors		Vented spike or male luer	Vented spike or male luer	Identical to predicate device
Output line connectors		Female luer lock	Male Luer Connector	Subject device output connector is to be connected to Set Gri-fill 2 Way (K050339) which is then connected to the final IV container. Predicate device is to be connected directly to the final IV container.
Final container		Vials, Infusion Bags (Gribag, Gri-flex), Syringes, Elastomeric pumps	Vials, Infusion Bags, Cassettes, Elastomeric pumps	Equivalent to predicate device
Shelf life		5 years	5 years	Identical to predicate device
Packaging		Individual packaging: Pouch Paper/Film PET-PP	Individual packaging: Pouch Tyvek / PET film	Different packaging materials
Materials	Tubing	Medical grade silicone. Platinum cured	Medical grade silicone. Platinum cured	Identical to predicate device
	Vented Spike	ABS	ABS	Identical to predicate device
	Spike filter	Filter: Acrylic copolymer	Filter: Acrylic	Identical to predicate

Characteristics		Gri-fill Peristaltic Set	Kiro Set – K152441 Predicate Device	Comparison
		Housing: Polypropylene	copolymer Housing: Polypropylene	device
	Spike cap	Polyethylene	Polyethylene	Identical to predicate device
	Luer-lock male barb connector	Polypropylene	Polycarbonate	Different to predicate device
	Luer-lock female barb connector	Polypropylene	Component not included in KIRO Set	Component not included in predicate device
	Luer-lock male connector cap	Polypropylene	Component not included in KIRO Set	Component not included in predicate device
	Luer-lock female connector cap	Component not included in Gri-fill Peristaltic Set	Polyethylene	Component not included in subject device
	Y- connector	Component not included in Gri-fill Peristaltic Set	Polycarbonate	Component not included in subject device

Table 1. Substantial Equivalence Comparison – Gri-Fill Peristaltic Set and Predicate Device (K152441)

Based on the results of comparison of intended use and technological characteristics, Gri-fill Peristaltic Set is substantially equivalent to the predicate device, Kiro Set. Any technological differences between Gri-fill Peristaltic Set and the predicate device have been demonstrated to raise no different questions of safety or effectiveness.

VII. PERFORMANCE DATA

Performance testing was conducted in accordance with "FDA Guidance for Industry and FDA Staff – Intravascular Administration Sets Premarket Notification Submissions [510(k)]" dated July 11, 2008 including the following specific testing:

Biocompatibility Testing

The biocompatibility evaluation for Gri-fill Peristaltic Set device was conducted in accordance with the FDA Guidance for Industry and FDA Staff - "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process'", June 16, 2016; ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process", as recognized by FDA; and FDA Guidance for Industry and FDA Staff - "Intravascular Administration Sets Premarket Notification Submissions [510(k)],"July 11, 2008. Biocompatibility testing as required for External Communicating Devices, Indirect Contact with the blood path, Limited Duration was conducted in accordance with cited guidances and standards.

The battery of testing included the following tests:

- Hemocompatibility – Hemolysis
- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous reactivity
- Acute systemic toxicity
- Material-mediated pyrogenicity

Sterility Testing

- Individual packaging validation according to ISO 11607-1.
- Ethylene oxide sterilization process validation according to ISO 11135:2014.
- Residuals of the ethylene oxide sterilization process according to ISO 10993-7:2008.
- Bacterial endotoxin testing based on ANSI/AAMI ST72:2002 and following FDA Guidance for Industry – Pyrogen and Endotoxins Testing: Questions and Answers.

Performance Testing

- Chemical, physical and functional performance testing was conducted as set out in the applicable parts of ISO 8536-4, including leakage and tensile strength testing. The applicable parts of ISO 22413 were also taken into account for chemical, physical and functional performance testing.
- Physical Testing of luer-locks was conducted as set out in the applicable parts of ISO 594-1 and ISO 594-2.
- Functionality, simulating worst case conditions (device and compounding system during 8 hours in continuous, nonstop) including determination of the accuracy of the dosage achieved (dose verification at different intervals) and tightness test. Also conducted in the stress stability study.

Summary discussion of non-clinical data:

Chemical, physical, mechanical and biological test data relevant to the new device are used to support the device biocompatibility and stability as well the applicable physical and mechanical specifications. Non-clinical bench testing performed on Gri-fill Peristaltic Set included leakage testing, flow-rate testing and functional checking as per its intended use. Final evaluation included specific testing for ethylene oxide sterilization process residuals, manufacturing process residuals, sterility and endotoxins on final finished sterilized devices. All tests yielded correct results.

Summary discussion of clinical data:

No clinical data presented in this submission.

VIII. CONCLUSIONS

Minor technological differences have been analyzed and the results of the bench testing conducted demonstrate the subject device is substantially equivalent to the predicate device in the intended use, indication for use and functionality .